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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,041	05/06/2004	Fabrizio Alessandro Maspero	1032553-000059	7765

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EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3775	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/840,041	MASPERO ET AL.	
	Examiner	Art Unit	
	Anu Ramana	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,15,16 and 41-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 15-16, and 41-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 15-16, and 47-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, the limitation, "said granules constituting a major weight fraction" is deemed to be new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 15, 16, 41-42, 47 and 51-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-12, 15 and 16, it is unclear what is meant by the term “major weight fraction.” Is it 10%, 20%, 40%, 50%, 90% or 95%?

In claims 41-42, 47 and 51-55, it is unclear what is meant by "regularly shaped and/or spherical." Are the regularly shaped particles spherical or not?

In claims 2 and 3, the phrase "and combinations thereof" renders the claims vague and indefinite because it is unclear which combination of materials is being claimed.

In claim 4, the phrase "and combination thereof" renders the claim vague and indefinite because it is unclear which combination of materials is being claimed.

In claim 7, the phrase "and co-polymers, terpolymers thereof and blends of those polymers" render the claim vague and indefinite because it is unclear which combination of particular materials or polymers is being claimed.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 43, 44 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Evans et al. (US 7241316).

Evans et al. disclose a moldable implant composition including: a plurality of biocompatible synthetic non-bone particles such as ceramics or calcium phosphate or calcium sulfate having a particle size of about 100 microns; a biocompatible polymer such as polylactide or polycaprolactone; a plasticizer such as caprolactone; and a biologically active substance such as a growth factor wherein the composition can be delivered by injection or preformed as an implant for surgical insertion (Figs. 15-18, col. 16, lines 20-61, col. 18, lines 63-67, col. 19 and col. 20, lines 1-51).

Claims 43, 44 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Ricci et al. (US 6770695).

Ricci et al. disclose an implantable or moldable composition including: synthetic calcium sulfate particles having a size greater than 20 microns; a biocompatible or biodegradable polymeric coating on the particles wherein the polymer is any type of resorbable polymer (for e.g. polylactides, polydixanones etc.), the weight of the polymer is about 0.1% to about 50% by weight and the thickness of the polymeric coating is 0.5

microns to 100 microns; a plasticizer such as acetone; and a setting agent such as water or saline (col. 3, lines 11-28 and col. 4, lines 5-47). Once solidified in a bone defect, the Ricci et al. composition forms a composite matrix with pores filled with air.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-9, 11-12, 16, 41-42, and 46-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. (US 6770695).

Ricci et al. disclose an implantable or moldable composition including: synthetic calcium sulfate particles having a size greater than 20 microns; a biocompatible or biodegradable polymeric coating on the particles wherein the polymer is any type of resorbable polymer (for e.g. polylactides, polydixanones etc.), the weight of the polymer is about 0.1% to about 50% by weight and the thickness of the polymeric coating is 0.5 microns to 100 microns; a plasticizer such as acetone; and a setting agent such as water or saline (col. 3, lines 11-28 and col. 4, lines 5-47).

Ricci et al. disclose particles with a size greater than 20 microns. Ricci et al. also disclose the weight of the polymer to be about 0.1% to about 50% by weight.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided particles with sizes in a range of about 100 microns to about 4000 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided polymer in a range of about 4% to about

20% by weight, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a polymeric coating thickness in a range of about 1 micron to about 300 microns, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. in view of Evans et al. (US 7241316).

Ricci et al. disclose all elements of the claimed invention except for alternate types of biocompatible ceramics.

Evans et al. teach the use of biocompatible ceramics such as various calcium phosphate salts (col. 20, lines 21-51).

The substitution of one known ceramic (various types of calcium phosphate) for another known ceramic (calcium sulfate as disclosed by Ricci et al.) would have been obvious to one of ordinary skill in the art at the time of the invention since this amounts to simple substitution of one known ceramic for another and would have yielded predictable results, namely, a biocompatible, implantable composition.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. in view of Meredith (US 7,001,551).

Ricci et al. disclose all elements of the claimed invention except for a biologically active substance.

It is well known to use a biologically active substance such as a growth factor in an implantable composition to enhance bone growth into a bone defect, as evidenced by Meredith (col. 9, lines 53-67 and col. 10, lines 1-26).

Therefore, it would have been recognized by one of ordinary skill in the art that applying the known technique of providing a biologically active substance such as a growth factor, taught by Meredith, in the Ricci et al. implantable composition would have yielded predictable results, i.e., improved repair of a bone defect by enhancing bone growth to seal the defect.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ricci et al. in view of Smestad (US 4430760).

Ricci et al. disclose all elements of the claimed invention except for the use of a microporous membrane.

It is well known to use a porous casing or membrane to contain filling material used to repair a bone defect, as evidenced by Smestad (col. 2, lines 57-68 and col. 3, lines 1-57).

Therefore, it would have been recognized by one of ordinary skill in the art that applying the known technique of providing a porous casing, as taught by Smestad, to hold the Ricci et al. material would have yielded predictable results, i.e., containment having a desired shape and size for sealing a bone defect.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US 7241316).

Evans et al. disclose all elements of the claimed invention except for the claimed weight percentage of the biocompatible polymer to be about 4% to about 20%.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the claimed weight percentages of biocompatible polymer, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments have been fully considered by the examiner.

Regarding the rejections under 35 USC 112 first paragraph of claims 1-12, 15 and 16, applicant's arguments are not persuasive because applicant's disclosure does not provide support for the respective weight fractions of the plasticizer and the synthetic non-polymeric granules in order to be able to make a determination of whether the granules constitute a major weight fraction of the implant composition or not. It is noted that "major weight fraction" does not meet the written description requirement because Applicant's disclosure as originally filed does not disclose the weight fraction.

Regarding the rejections of claims 43-45 under 35 USC 102(e) over Evans et al., applicant's arguments with respect to the "relatively minor fraction of calcium sulfate clearly does not form a structural matrix" are not pertinent because any component of a matrix, no matter how major or minor, is part of and thus forms the matrix. Other claimed features are clearly disclosed by Evans et al. as discussed in this office action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
June 25, 2009

/Anu Ramana/
Primary Examiner, Art Unit 3775